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1050 CONNECTICUT AVENUE, N.W.			WILLIAMS, LELA	
SUITE 400 WASHINGTON, DC 20036			ART UNIT	PAPER NUMBER
			1789	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)	
	10/553,760	HONKANEN ET AL.	
Office Action Summary	Examiner	Art Unit	
	LELA S. WILLIAMS	1789	
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet wi	h the correspondence address	
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailinearned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNIC 36(a). In no event, however, may a re will apply and will expire SIX (6) MON' e, cause the application to become AB.	ATION. ply be timely filed FHS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).	
Status			
1) ☐ Responsive to communication(s) filed on <u>09 D</u> 2a) ☐ This action is FINAL . 2b) ☐ This 3) ☐ Since this application is in condition for allowa closed in accordance with the practice under <u>B</u>	s action is non-final. nce except for formal matte	·	
Disposition of Claims			
4) ☐ Claim(s) 1.3-5.7-32 and 35 is/are pending in the 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1.3-5.7-32 and 35 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.		
Application Papers			
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to be drawing(s) be held in abeyantion is required if the drawing(ce. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea * See the attached detailed Office action for a list	ts have been received. ts have been received in Aprity documents have been u (PCT Rule 17.2(a)).	oplication No received in this National Stage	
Attachment(s) 1) Notice of References Cited (PTO-892)	4\ ☐ Interview S	ummary (PTO-413)	
2) Notice of Preferences Cried (PTO-592) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Date formal Patent Application	

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2010 has been entered.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claims 1, 3-5, 7-32, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant incorporates the statement "providing an amount of sweetening agent that is insufficient to entirely mask the bitter, sour and/or astringent taste of the edible product"; however there appears to be no support for said "insufficient" language in the present specification, thereby raising a USC 112, first paragraph issue.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4, 7, 8, and 32, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarama et al. WO 01/54686.

Regarding claims 1, 3, 7, 8, and 35; Sarama teaches a method for producing an edible product comprising a sweetening agent (page 27, third paragraph), and a plant sterol/stanol ester (page 7, third paragraph). The sweetening agent inherently has the characteristic properties to mask a bitter, sour and/or astringent taste. Given that Sarama discloses the use of sweetening agent in an amount that overlaps that used in the present invention, i.e. 0.1% to 20% (page 28, line 1), it is clear that the sweetening agent is present in amount that is insufficient to entirely mask the bitter, sour and/or astringent taste. The plant sterol/stanol esters component of the reference is present in an amount of 0.0001% to 25% (page 8, third paragraph). Sarama states that a combination of sterols/stanols is able to disguise adverse flavors (page 8, first paragraph) but does not disclose the ester "is effective to mask the bitter, sour, and/or astringent taste of the edible product". However, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently be "effective to mask the bitter, sour, and/or astringent taste of the edible product".

Regarding claims 4, Sarama discloses a method as applied to claim 1 wherein the sweetening agent comprises carbohydrates and non-carbohydrates (page 28).

Regarding claim 32, Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% into an edible product, which will inherently mask a bitter, sour and/or astringent taste of a product which comprises a sweetening agent. The sweetening agent inherently has the

characteristic properties to mask a bitter, sour and/or astringent taste. Given that Sarama discloses the use of sweetening agent in an amount that overlaps that used in the present invention, it is clear that the sweetening agent is present in amount that is insufficient to entirely mask the bitter, sour and/or astringent taste. Sarama states that a combination of sterols/stanols is able to disguise adverse flavors (page 8, first paragraph) but does not disclose the ester "is effective to mask the bitter, sour, and/or astringent taste of the edible product". However, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently "effective to mask the bitter, sour, and/or astringent taste of the edible product".

Claim Rejections - 35 USC § 103

- 6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 7. Claim 5, 9, 11-12, 20-23, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. WO 01/54686.

Regarding claim 5, Sarama discloses a method as applied to claim 4 above, wherein carbohydrate or non-carbohydrate sweetener agents are added to the product in the amount of 0.1% to 20% (page 28, line 1). The reference does not give the specific amount of each agent used, but does state the amount of sweetener will depend on the particular sweetener used and the sweetness intensity desired (page 27, third paragraph). Given this information, the determination of the amount of sweetener would be considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly,

one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of each sweetener needed to obtain the desired product (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding claim 9, Sarama discloses a method as applied to claim 1, to be a beverage, such as teas, colas, fruit juice, or near-water (page 21, fourth paragraph). The reference does not teach the viscosity of said beverages; however, they are drinks known to be of low viscosity. Knowing that these drinks are usually "thin" and greatly accepted by the consumer as being so, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the beverages to have a low viscosity in the Pascal range including as presently claimed, in order to produce a beverage with the known desired thinness/thickness of the final beverage.

Regarding claims 11, 12, 20-23, 29, 30, and 31, Sarama discloses beverage and food products, i.e. milk and juice drinks, ice cream (page 21, third paragraph), which comprises plant sterol ester and a carbohydrate or non-carbohydrate sweetening agent. Sarama discloses that the plant sterol ester compound is particularly useful in such beverages as those containing 0.1% to 40% fruit juices or fruit flavors (berries and citrus are explicitly listed in paragraph 2, page 25) milks, coffees, teas, and fortified drinks e.g. a liquid meal replacement (page 21, 3rd para.-page 22, 1st para.). The reference also teaches adding flavors such as chocolate (page 26, second paragraph). The disclosure of a "milk based [flavor] drink" is not explicitly stated; however, given the disclosure of the drinks/flavors, it would have been obvious to one of ordinary skill to

combine milk with chocolate to yield a milk based cocoa drink or milk with coffee thus yielding a milk based coffee drink. The mixtures of milk/cocoa and milk/coffee are beverages that have long been established and accepted.

The specific amounts of plant sterol and carbohydrate or non-carbohydrate sweetening agents used in the individual drinks/food products are not disclosed and the amount of citrus fruit juice falls slightly outside of the claimed range of at least 50%; however the general ranges of 0.0001% to 25% of plant sterol/stanol esters and 0.1% to 20% of carbohydrate or non-carbohydrate sweetening, which include sucrose (page 28) are given, it would have been within the skill level of one of ordinary skill in the art to develop a beverage, including the presently claimed beverage, with a suitable amount of additives, including citrus fruit juice, to achieve the desired taste of the final product.

One of ordinary skill would have optimized, by routine experimentation, a desired amount of plant sterol, sweetener, either carbohydrate or non-carbohydrate, and fruit juice (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). As such, without showing unexpected results, the claimed amount cannot be considered critical.

The sweetening agent, including sucrose, inherently has characteristic properties to mask a bitter, sour and/or astringent taste. Given that the amount of sweetener agent used overlaps that presently claimed, it is clear that the sweetening agent is present in amount that is insufficient to entirely mask the bitter, sour and/or astringent taste. Although Samara does not disclose the ester "in an amount that, in combination with the carbohydrate sweetening agent, is effective to mask

the bitter, sour, and/or astringent taste", given that the reference discloses the presence of plant sterol/stanol esters and sweeteners in amounts as presently claimed, the ester will naturally be "effective to mask the bitter, sour, and/or astringent taste of the edible product".

It is noted that the amount of sweetening agent in Samara is not that presently claimed for the non-carbohydrate sweetener in claim 23; however given that it is known in the art that non-carbohydrate sweetener are used in a lesser amount than carbohydrate sweeteners due to their potency, and given that the reference states "[t]he amount of sweetener used in the composition of the present invention typically depends upon the particular sweetener used and the sweetness intensity desired. For no/low calorie sweeteners, this amount varies depending upon the sweetness intensity of the particular sweetener." (p.27, 3rd para.), it would have been obvious to one of ordinary skill in the art to optimize an amount of non-carbohydrate sweetener which is "insufficient to entirely mask the bitter, sour and/or astringent taste" of the drink.

8. Claims 10 and 13-18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sarama et al. WO 01/54686 in view of Yoon et al. WO 02/28204.

Regarding claim 10, 13-18, Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% and a carbohydrate in an amount of 0.1% to 20% to a milk beverage (page 21, 3rd para.-page 22, 1st para.) and other dairy products such as ice cream, milkshakes, and milk products (page 21, 3rd para.). The sweetening agent inherently has characteristic properties to mask a bitter, sour and/or astringent taste and given that the amount of sweetener agent used overlaps that presently claimed, it is clear that the sweetening agent is present in amount that is insufficient to entirely mask the bitter, sour and/or astringent taste. Although Samara does not

disclose the ester "in an amount that, in combination with the carbohydrate sweetening agent, is effective to mask the bitter, sour, and/or astringent taste", given that the reference discloses the presence of plant sterol/stanol esters and sweeteners in amounts as presently claimed, the ester will naturally be "effective to mask the bitter, sour, and/or astringent taste of the edible product".

It is noted that the amount of sweetening agent in Samara is not that presently claimed for the non-carbohydrate sweetener in claims 14, 16, and 18; however given that it is known in the art that non-carbohydrate sweetener are used in a lesser amount than carbohydrate sweeteners due to their potency, and given that the reference states "[t]he amount of sweetener used in the composition of the present invention typically depends upon the particular sweetener used and the sweetness intensity desired. For no/low calorie sweeteners, this amount varies depending upon the sweetness intensity of the particular sweetener." (p.27, 3rd para.), it would have been obvious to one of ordinary skill in the art to optimize an amount of non-carbohydrate sweetener which is "insufficient to entirely mask the bitter, sour and/or astringent taste" of the drink.

It is noted that the presently claimed amount of non-carbohydrate in claims 14, 16, and 18 is less than that disclosed by Sarama, however, as the flavor is a variable that can be modified, among others, by adjusting the amount of the additives or the type of sweetener, the precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of plant sterol ester and sweetener agent in Sarama to obtain the desired flavor (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general

conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). Therefore, given the presently claimed amount could have been determined by one of ordinary skill in the art without undue experimentation, the presently claimed amount is not considered to confer patentability to the claims.

Sarama disclosure of a milk beverage/products and additive amounts are general and it does not specifically list a cereal milk based drink/product, soy products, or the specific amounts of sweetener agent.

Yoon teaches adding plant sterol to various beverages (page 1, line 5) including water, juices, coffee, tea, milk, and soy milk (page 9, line 30).

Given that the reference teaches the use of soy milk, as well as juices and coffee, it would have been obvious to one of ordinary skill in the art to combine soy with the other milk beverages/ products to enhance the nutritional value of fruit juice and coffee drinks.

9. Claims 19, 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. WO 01/54686 in view of Vulpson et al. WO 00/41491.

Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% and a sweetener agent in an amount of 0.1% to 20% to a milk beverage. The sweetening agent naturally has characteristic properties to mask a bitter, sour and/or astringent taste and although Samara does not disclose the ester "in an amount that, in combination with the carbohydrate sweetening agent, is effective to mask the bitter, sour, and/or astringent taste", given that the reference discloses the presence of plant sterol/stanol esters and carbohydrate sweetener in

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amounts as presently claimed, the plant sterol/stanol esters will naturally be "effective to mask the bitter, sour, and/or astringent taste of the edible product".

It is noted that the amount of sweetening agent in Samara is not that presently claimed for the non-carbohydrate sweetener in claims 25 and 28; however given that it is known in the art that non-carbohydrate sweetener are used in a lesser amount than carbohydrate sweeteners due to their potency, and given that the reference states "[t]he amount of sweetener used in the composition of the present invention typically depends upon the particular sweetener used and the sweetness intensity desired. For no/low calorie sweeteners, this amount varies depending upon the sweetness intensity of the particular sweetener." (p.27, 3rd para.), it would have been obvious to one of ordinary skill in the art to optimize an amount of non-carbohydrate sweetener which is "insufficient to entirely mask the bitter, sour and/or astringent taste" of the drink.

It is noted that the presently claimed amount of non-carbohydrate in claims 25 and 28 is less than that disclosed by Sarama, however, as the flavor is a variable that can be modified, among others, by adjusting the amount of the additives or the type of sweetener, the precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of plant sterol ester and sweetener agent in Sarama to obtain the desired flavor (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). Therefore, given the

presently claimed amount could have been determined by one of ordinary skill in the art without undue experimentation, the presently claimed amount is not considered to confer patentability to the claims.

Sarama's disclosure of a milk beverage and additive amounts are general and it does not specifically list a fermented milk based drink or the type of sweetener agent.

Vulpson teaches adding plant sterols to fermented milk products such as yoghurt (page 1, line 12). The reference discloses a yoghurt product based on whey protein and plant sterols (page 23, lines 21-23) and also discloses the use of soymilk in the yoghurt process (page 35, line 2). The reference does not expressly disclose a cereal-based yoghurt product, however it does teach that "rice and soybeans are the most common raw materials for the production of fermented foods in many Eastern countries" (page 7, line 17-20). Therefore, given it is disclosed as common knowledge in the art to have rice (which is a cereal) based yoghurt products, one of ordinary skill in the art would have found it obvious to produce cereal-based yoghurt.

One of ordinary skill in the art would have been motivated to combine the teaching of Sarama with those of Vulpson in order to produce a food/drink product which has not only good taste but also added health benefits.

Response to Amendment

- 10. Claims 1, 3-5, 7-32, and 35 are currently pending. Claims 2, 6, 33 and 34 are cancelled.
- 11. Applicant's amendment is sufficient to overcome the 35 U.S.C. §112, second paragraph and 35 U.S.C §101 rejections set forth in the previous office action; therefore the rejection has been withdrawn.

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Response to Arguments

12. Applicant's arguments filed December 9, 2010 have been fully considered but they are not persuasive.

13. Applicant states:

Applicants submit, however, that Sarama does not disclose the particular steps of providing an amount of sweetening agent that is insufficient to entirely mask the bitter, sour and/or astringent taste of the edible product, and adding a plant sterol ester in an amount that, in combination with the sweetening agent, is effective to mask the bitter, sour, and/or astringent taste of the edible product. Rather, Sarama discloses that the combined plant sterol ester and L-arginine is added directly to finished edible products with sufficient plant sterol ester to mask the L-arginine. See page 20, paragraph 4. (Page 21-22)

It is noted that Sarama does not explicitly state the sweetener is provided in an amount that is insufficient to mask taste and that the combination of the sweetener and ester is effective in masking taste; however, given that the reference discloses the presence of plant sterol/stanol esters and carbohydrate sweetener in amounts as presently claimed, the plant sterol/stanol esters will naturally be "effective to mask the bitter, sour, and/or astringent taste of the edible product".

Applicant further states that "even if Sarama teaches the same range of plant sterol ester recited by claim 1, the step of providing an amount of sweetening agent that is insufficient to mask a bitter taste of the edible product is not necessarily present in Sarama." However, given that the reference teaches the presently claimed amount of sweetening agent, the sweetening agent would naturally be insufficient to mask a bitter taste of the edible product. It is common sense that identical sweeteners, in identical amounts, will have identical properties.

Also, it is acknowledged that Applicant makes multiple references to the disclosure of L-arganine in Samara, while the reference does, this point is irrelevant given there is nothing in Applicant's present open claim language, i.e., comprising, which does not allow for this.

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14. Regarding Applicant's remarks of:

While Sarama does teach products having sweetening agent, Sarama never contemplates using less sweetening agent than necessary to mask a bitter taste because the edible product is already intended to have a pleasurable taste.(p.23)

Samara may not contemplate said action; however, the reference does utilize the presently claimed amount of sweetener which will naturally be insufficient to entirely mask a bitter taste.

15. Applicant argues:

Due to the fact that Sarama teaches a pre-made composition which is added to an existing food product, the recited method steps would not be inherently performed by Sarama. First, because the sterol range disclosed by Sarama is described relative to the L-arganine/sterol mixture, the sterol composition taught by Sarama does not teach the overall percentage of the sterol present in the edible product. (p.23)

Applicant is arguing the sterol as weight percent of the edible product; however, the present claim states the addition of sterol to be 0.2 to 25% by weight. Even if Samara does not teach the overall percentage of the sterol present in the final edible product, 0.0001-25% of sterol is utilized.

- 16. Regarding page 24, it is noted that the reference does not teach having less than enough sweetener will mask taste; however the reference does overlap amounts presently claimed and therefore said limitation is taught.
- 17. Regarding applicant's argument of Yoon (WO 02/28204), note that while Yoon does not disclose <u>all</u> the features of the present claimed invention, the reference is used as a teaching reference, and therefore, it is not necessary for the secondary references to contain all the features of the presently claimed invention, In re Nievelt, 482 F.2d 965, 179 USPQ 224, 226

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(CCPA 1973), In re Keller 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather Yoon is used teach a certain concept, namely that plant sterols are known to be added to various edible products, and in combination with the primary reference, discloses the presently claimed invention.

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18. Regarding applicant's argument of Vulpson (WO 00/41491) note that while Vulpson does not disclose <u>all</u> the features of the present claimed invention, the reference is used as a teaching reference, and therefore, it is not necessary for the secondary references to contain all the features of the presently claimed invention, In re Nievelt, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), In re Keller 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather Vulpson is used teach a certain concept, namely that plant sterols are known to be added to fermented milk, rice, and soya yoghurt products, and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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LELA S. WILLIAMS Examiner, Art Unit 1789

/L. S. W./

/Callie E. Shosho/ Supervisory Patent Examiner, Art Unit 1787